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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,043	10/31/2003	Helle Weibel	6206.210-US	1198

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,043	WEIBEL ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) *1-11,14-17,20 and 21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendments and arguments, filed 11/9/2006, have been received and entered into the record. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. Upon further consideration the following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. In light of the new grounds of rejection this Office Action is Non-Final.

Status of the Claims

Claims 1-21 are currently pending and are the subject of this Office Action. Claim 1 is presently amended.

Claim Objections

Claims 1-11 are objected to because of the following informalities: it appears that the active agent is misspelled. Claim 1 recites, "5-[[4-[**13**-methyl]-". Elsewhere, the compound is identified as "5-[[4-[**3**-methyl]-".

Claims 14-17 are objected to because the claims do not end in a period.

Claims 20-21 are objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, claims 20 and 21 depend from claim 1 which recites a composition having water content below 1%. However, claims 20 and

21 recite the composition of claim 1 "diluted with 92 mL water before use". Thus, claims 20 and 21 do not further limit claim 1 because water is being **added** to the compositions of the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-2, 5-7, 10-17 and 19-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 97/41097 (prior art of record).

WO '097 at page 34, lines 27-29, page 35, Examples and page 7, lines 13-14 disclose pharmaceutical compositions comprising applicants' active agent that can be formulated in tablets, capsules, or powder form (dry form) and can be combined with pharmaceutically acceptable excipients such as magnesium stearate, lactose, carboxymethyl cellulose, corn starch, flavourants, sweeteners and other carriers and excipients routinely employed in preparing pharmaceutical compositions. The reference also discloses that the pharmaceutical compositions

contain from 1 to 20% by weight active compound and the remainder of the composition is pharmaceutically acceptable carriers, excipients, diluents or solvents (page 35, lines 1-3).

The reference does not expressly disclose compositions containing below 1% water or the proportions of excipients set forth in the instant dependent claims.

However, once the general conditions of a pharmaceutical composition are known in the art, it is well within the level of ordinary skill in the art to modify said compositions by optimizing the amounts of excipients and excipients utilized. Moreover, the reference discloses ranges of 1 to 20% active compound, the remainder of the composition being pharmaceutically acceptable carriers, diluents or solvents. One of ordinary skill in the art would have been motivated to optimize the types and amounts of excipients to make the most stable and easily formulated composition. With regard to claims that recite specific concentration and ratios of the components, it is the position of the examiner that such limitations do not impart patentability absent a showing of criticality. The prior art discloses compositions comprising the active agent and pharmaceutically acceptable excipients. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

Further, tablets, capsules and powder formulations are considered in the art to be "dry" compositions. As such, it is expected that these compositions will have low water content. Applicants have presented no evidence that water content of "below 1%" results in a composition having unexpectedly superior properties compared to the compositions disclosed in the WO '097 reference.

As such, in the absence of a showing of unexpected results commensurate in scope with the claims, the instantly claimed pharmaceutical compositions would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 3-4, 8-9 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 97/41097 as applied to claims 1-2, 5-7, 10-17 and 19-21 above, and further in view of Svensson *et al.* (U.S. Patent No. 5,866,590; Issued Feb. 2, 1999) (prior art of record).

The instant claims recite pharmaceutical compositions comprising 5-[[4-[3-methyl]oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione and further comprising an antioxidant.

WO '097 discloses as discussed *supra*.

Svensson *et al.* disclose pharmaceutical compositions containing tiagabine hydrochloride (Abstract; col. 1, lines 13-23; col. 2, lines 21-52). The compositions further comprise an antioxidant and are disclosed to have low water content (col. 2, lines 50-65).

As discussed *supra*, once the general conditions of a pharmaceutical composition are known in the art, it is well within the level of ordinary skill in the art to modify said compositions by optimizing the amounts of excipients and excipients utilized. As such, it would have been *prima facie* obvious to one of ordinary skill in the art that the pharmaceutical compositions disclosed in Svensson *et al.* could be predictably used with any active agent, including the agent instantly claimed and disclosed in WO '097.

Further, WO '097 discloses that the active agents may be formulated with any pharmaceutically acceptable excipients. One skilled in the art would recognize that the

formulations disclosed in Svensson *et al.* contain well-known excipients. As such, it would have been well within the level of ordinary skill in the art to substitute other known active agents in the pharmaceutical compositions disclosed in Svensson *et al.*

Thus, in the absence of a showing of unexpected results commensurate in scope with the claims, the instantly claimed pharmaceutical compositions containing an antioxidant would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-7, 9, 11-13, 16 and 28-31 of copending Application No. 09/450,609. Although the conflicting claims are not identical, they are not patentably distinct from each other because the composition of the instant invention encompasses the composition of the copending application. The instant claims and the claims of the copending application overlap because they are both claiming a pharmaceutical composition comprising the same active agent, same excipients, and low water content.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson, Ph.D.
Patent Examiner
AU 1614

February 16, 2007